Contains No CBI



"LED ON aniatroof"

HEALTH. ENVIRONMENT AND SAFETY



August 24, 1992

Compliance Audit Program CAP ID#: 8ECAP-0075

OTS CBIC

8EHQ-92-125

CERTIFIED MAIL - RETURN RECEIPT

Document Processing Center (TS-790) Office of Pollution Prevention and Toxics Environmental Protection Agency 401 M Street, SW Washington, D. C. 20460

INIT

Attn

Section 8(e) Coordinator

(CAP Agreement)

Gentlemen:

Phillips Petroleum Company is submitting the enclosed sixty (60) reports (two boxes, numbered 1 and 2) of toxicological studies pursuant to catagory II.B.2.b of the CAP Agreement 8ECAP-0075 Reports. Reports being submitted contain no confidential business information.

We are sending an additional five boxes (box numbers 3-7) of reports of studies that have, previously, been submitted to the FYI coordinator of the Office of Pollution Prevention and Toxics by the American Petroleum Institute (API). These are being provided solely for the Agency's convenience.

For questions concerning this correspondence, plese contact Fred Marashi at 918-661-8153.

Very truly yours,

Barbara J. Price

Vice President

Health, Environment & Safety

Enclosure (Seven Boxes)

FFM/dh:29

Contains No CBI



"Contains NO CEI"

HEALTH, ENVIRONMENT AND SAFETY

August 24, 1992

Compliance Audit Program CAP ID#: 8ECAP-0075

NTS CBIC

CERTIFIED MAIL - RETURN RECEIPT

Document Processing Center (TS-790)
Office of Pollution Prevention and Toxics
Environmental Protection Agency
401 M Street, SW
Washington, D. C. 20460

Attn:

Section 8(e) Coordinator

(CAP Agreement)

Gentlemen:

Phillips Petroleum Company is submitting the enclosed sixty (60) reports (two boxes, numbered 1 and 2) of toxicological studies pursuant to catagory II.B.2.b of the CAP Agreement 8ECAP-0075 Reports. Reports being submitted contain no confidential business information.

We are sending an additional five boxes (box numbers 3-7) of reports of studies that have, previously, been submitted to the FYI coordinator of the Office of Pollution Prevention and Toxics by the American Petroleum Institute (API). These are being provided solely for the Agency's convenience.

For questions concerning this correspondence, plese contact Fred Marashi at 918-661-8153.

Very truly yours.

Barbara J. Pricé Vice President

Health, Environment & Safety

Enclosure (Seven Boxes)

FFM/dh:29



-

Phillips Petroleum Company

Contains No CBI

CAP Identification Number: 8ECAP-0075 Pursuant to Category: II.B.2.b 42

Title of Study: Subacute Dermal Toxicity API 78-8 #6 Heavy Fuel Oil (API Gravity 23.1/0.2% S)

Name of Chemical: No. 6 Heavy Fuel Oil (API Gravity 23.1/0.2% S)

CAS#: 68553-00-4

Summary: Dermal application of No. 6 Heavy Fuel Oil 5 days per week for two weeks produced

histopathological changes in the liver and urinary bladder in the rabbit.

Contact:

Project No. 1443-F

Subacute Dermal Toxicity API 78-8 #6 Heavy Fuel Oil (API Gravity 23.1/0.2%S)

OBJECTIVE:

The study described herein was conducted to evaluate the dermal toxicity of the test material when applied in repeated doses over a period of two weeks.

MATERIALS AND METHODS:

1. Test Material:

The test material, a viscous liquid in a metal container identified as API 78-8, #6 Heavy Fuel Oil (API Gravity 23.1/0.2%S), was received by Elars on October 8, 1979. The concentration, purity, and stability were not provided by the sponsor. The test material was stored in Elars test material storage room.

2. Animals:

The dose group and the control group consisted of eight adult New Zealand White rabbits, four males and four females, weighing between 2 and 4 kg. The rabbits were purchased from Stevinson Rabbitry, Stevinson, California, Pel-Freez Farms, Rogers, Arkansas, and Elkhorn Rabbitry, Elkhorn, California, and were identified individually by metal ear tags and corresponding cage tags. The rabbits were allowed to acclimate at Elars at least one week. Purina Rabbit Chow® and fresh water were provided ad libitum. Throughout acclimation and testing, the rabbits were housed individually in standard laboratory rabbit cages.

2

Project No. 1443-F August 8, 1980

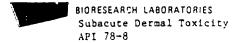
3. Method:

Prior to application of test material, the rabbits were shaved free of hair with a number 40 Oster[®] clipper blade. The shaved area on each animal constituted about 30 percent of the total body surface area.

The daily dosage used for this compound was 8 ml/kg body weight, and an untreated control group. The rabbits were exposed to the test material for five consecutive days followed by a two day rest period and then again for five consecutive days. The test material was applied to four-inch square gauze sponges backed by plastic wrap. The sponges and plastic wrap were taped to the shaved area of the animals' back with porous adhesive tape. The entire trunk of each rabbit was wrapped with elastic tape to prevent slippage of the patches. The rabbits remained bandaged for 24 hours, at which time the patches were removed and a new dose of test material was applied. This procedure was followed each day of the five day dosing period. During the two day rest period the animals were not dosed.

Observations for mortality, local reactions, and behavioral abnormalities were made daily during the 14 day period. Initial and final body weights were recorded.

Any animals which succumbed during the study as well as those killed with T-61[®] at the termination of the study were subjected to necropsy, and all significant gross pathological alterations were recorded. In addition, the following tissues were submitted for histopathologic examination: skin from the test site, liver, kidney, spleen and urinary bladder.



Project No. 1443-F August C 1980

The collected tissues were fixed in 10% neutral buffered formalin. Afterwards, the tissues were trimmed, embedded in paraffin, sectioned at 4 to 5 microns, affixed to glass slides, and stained with hematoxylin and eosin. Histopathologic examination of the submitted tissues was conducted at Westpath Laboratories by William H. Halliwell, D.V."., Ph.D., Diplomate: ACVP.

3

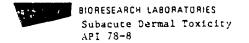
RESULTS:

Individual animal weights and doses are given in Tables 1 and 2 for the 8 ml/kg dosage level and the control, respectively. The most significant daily observation recorded at the 8 ml/kg test level was erythema and irritation at the test site. Observation was difficult due to the staining of the test site by the test material.

The animals in the 8 ml/kg group showed decreased appetites and became emaciated, with an average weight loss of 0.48 kg; this dosage group produced 25% mortality. An average weight gain of 0.20 kg was observed for the control group; no mortality was observed.

The gross postmortem examinations of treated rabbits that died on study showed one rabbit with a swollen, necrotic liver and congested kidneys. A second rabbit exhibited a yellow discolored, friable liver and a large mass of clotted blood from the descending colon. Gross necropsy of rabbits surviving the 14-day observation showed all rabbits with abnormal liver observations including livers that were pale, yellow, congested or mottled. Also, two rabbits exhibited pale kidneys, two rabbits had congested kidneys, and two rabbits had enlarged spleens.

The histopathologic diagnoses of selected tissues from rabbits exposed to 8 ml/kg of test material API 78-8 and from untreated control rabbits are



Project No. 1443-F August 8, 1980

presented in Tables 3 and 4, respectively. The test material produced, at the test site (skin): scanthosis, chronic inflammation, crusting, dermal congestion, dermal edema, and hyperkeratosis that varied in severity from very slight to moderate.

The liver from seven of eight treated rabbits contained evidence of multifocal necrosis that varied in degree of insult from very slight to severe. Three of the same treated rabbits revealed centrilobular vacuolar degeneration in the liver that varied in severity from very slight to slight. Evidence of epithelial hyperplasia of the urinary bladder mucosa was diagnosed in four of the eight animals that varied in severity from very slight to slight.

CONCLUSIONS:

The test material, API 70-8, #6 Heavy Fuel Uil (API Gravity 23.1/0.2%S), caused slight dermal irritation and resulted in obvious treatment-related signs during the 14 day observation period and at necropsy in the species examined.

Histopathologic examination of tissues from rabbits exposed to 8 ml/kg of the test material (API 78-8) revealed evidence of dermal and hepatic toxicity and proliferative changes in the transitional epithelium of the urinary bladder. These changes were attributed to exposure of the test material.

The dermal LD50 for the test material is greater than 8 ml/kg.

PERSONNEL:

Personnel responsible for the collection and interpretation of data generated in the course of this study were Vicki J. Mills, B.S., Toxicology Technician, Study Coordinator; L. Steven Beck, D.V.M., M.S., Assistant



BIORESEARCH LABORATORIES
Subacute Dermal Toxicity
API 78-8

Project No. 1443-F August 8, 1980

Director of Toxicology, Study Director; Denice E. Morita, B.S., Irma Albinana, and Kris L. Hansen, B.S., M.S., Toxicology Technicians; Terry A. Hewett, B.S., Laboratory Assistant; Douglas I. Hopler, Ph.D., Director of Toxicology; and William H. Halliwell, D.V.M., Ph.D., Pathologist.

RAW DATA:

Raw data regarding this study are to be found in Elars' notebooks #239 and #1505 in file #1443-F.

enter un un voir l'ennon<mark>ement ingentité de l'ente</mark>

6

Project No. 1443-F August 8, 1980

Table 1
Individual Animal Weights and Dosages
Dosage Level 8 ml/kg, 25% Mortality
May 26, 1980

Animal Number	Sex	Body Wt. Day O (kg)	Dose (ml)	Body Wt. Terminal	Weight Gain (kg)	Termination Day
969	м	3.4	27.2	2.9	-0.5	14
985	м	3.9	31.2	3.6	-0.3	9
987	м	3.2	25.6	2.8	-0.4	14
1123		2.6	20.8	2.3	-0.3	14
954	r F	3.9	31.2	3.2	-0.7	14
958	F.	3.3	26.4	2.7	-0.6	14
962	F	3.3	26.4	2.6	-0.7	14
964	F	2.8	22.4	2.5	-0.3	8

Table 2
Individual Animal Weights and Dosages
Dosage Level Control, 0% Mortality
May 21, 1979

Animal Number	Sex	Body Wt. Day O (kg)	Dose	Body Wt. Terminal	Weight Gain (kg)	Termination Day
421	м	2.4		2.5	0.1	14
	М	2.3		2.7	0.4	14
423		2.4		2.5	0.1	14
425	M	2.5		2.7	0.2	14
427	Ж	2.7		2.9	0.2	14
422	F -	2.7		3.0	0.3	14
424	F	2.7		2.9	0.2	14
426	F		_	2.5	0.1	14
428	F	2.4		2.0		

Westpath Laboratories, Inc. Project Number 1014

Table 3

Elars Bioresearch Laboratories Project Number 1443-F API 78-8

INDIVIDUAL HISTOLOGIC OBSERVATIONS

8 ml/kg/day

Accession Number (80-)	1142	1143	1144	1145	1146	1147	0148	1149		
Animal Number	985	987				964				
Sex	У.	M	M	м	F	17	F	F		
Reason Discontinued	DOT		FS	FS	FS	DOT	FS	FS		
Davs on Test	9	14	14	14	14	8	14	14		
Test Site (Skin)		 	-			 	-			
	2	3	3	1 3	3	3	3	3		
Acanthosis	2	2	2	2	3	1	2	3		
Chronic Inflammation		 		 	1	 	 			
Crusting	2	1	2	2	2	3	3	2		
Dermal Congestion	2	2	2	2	3	2	2	3		
Dermal Edema	2	2	2	2	3	2	2	3		
Hyperkeracosis	 	 		NR		+	NR	-		
Kidney			 - -	NK	2	1 2	I MA	3		
Congested	3_	2	2	 	 -	+ -	 	2		
Mononuclear Cell Infiltrate, Diffuse		3	ļ	ļ			-	1 2		
Liver	ļ	ļ		NR	 	 	↓	 		
Cyst, Parasitic	ļ	 	2	·	 	 	↓			
Mineralization	<u> </u>	2	<u> </u>		1		1			
Necrosis, Multifocal	3	2	1 1	1	<u> </u>	3_	4	2		
Pericholangitis	3	2	2		1	2	2	2	<u></u>	
Vacuolar Degeneration, Centrilobular	<u> </u>	1_1_	<u> </u>	1	1 1		2			
Spleen	<u>i</u>		<u> </u>	NR	NR	NR	NR			
Congested	2	2	3_				<u> </u>	. 3		
Urinary Bladder	NR		l		NR		NR	NR		
Hyperplasia, Epithelial		2	2	1		2	ì	Ī		
									I	
	Ţ					T		1		
			1	1						
	1	1			1					
			1	1		1	7	1		
		1	1							
			1	1		1		1		
	 	1	1	 	1			1		
<u> </u>	 	 	1	 	† — —				 	
	+	+	1	1	†					
	+	+	1	+	+	1	1	1		
	+	+		+	 	1	1		 	T
	+	 	+	 	+			1	 	
	+	+	+	+	+	+		1	 	
	+	+	+	+	 	+	+	+	 	-
	+	+	1	+	+	 	+	1	 	
	+	 	+	+	+		1	 	1	1
	+	+			+			+	+	1

KEY: Acc = Accidental Death

DOT = Died on Test

FS - Final Sacrifice

MS = Moribund Sacrifice SS = Scheduled Sacrifice

NDT - Tissue Present, No

Diagnosis Tendered

TNP - Tissue Not Present

NR = Tissue Present, Not

Remarkable

AUT - Autolysis

O-NR - Paired Organ, Unilateral

Absence, Tissue Present,

Not Remarkable 0- - Unilateral Lesion

<u>Severity</u>

1 - Very Slight

2 = Slight or Small

3 = Moderate

4 - Severe

Westpath Laboratories, Inc. Project No. 1014

3 Table 4 Elars Bioresearch Laboratories Project Number 1443-F API 78-8

INDIVIDUAL HISTOLOGIC OBSERVATIONS

Control

	N225	11226	2122	7 82	28	N229	N 2 30	N2:	31 N	232		
cession Number		422		3 4	24	425	426	4	27	428		
nimal Number	421	422 F		H -	F	M			н	F		
ex	M	FS	1	S	FS	FS	FS	1	FS	FS		1
esson Discontinued	FS 14			4	14	14	14	1	14	14		
avs on Test	1 14	1 14		TR -		NR	NR	. 1				
IVER	 	 	 		4			1	4			
Abscess, focal		 	+-	_								
Congested			╅─				1	1				Д
Mineralization	}	 		\dashv			1					
Necrosis, multi: cal	1	13	+-							1		→
Pericholangitis	+ - 3		_	_		!						
Vacuolar Degeneration, centrilobular	NR		,	NR	NR	NR	N	R	NR	NR	<u> </u>	
KIDNEY	+ NK	1 35	-	310	11.53	1					<u> </u>	
Congested			+-			1		\perp			↓	
Mineralization, focal	+	+		_								
Mononuclear Cell Infiltrate, focal				_							↓	
Mononuclear Cell Infiltrate, diffuse			+-							<u> </u>	<u> </u>	
Nephrosis, tubular			-	NR		NI	R I N	R		NR		
SPLEEN		+							3			
Congested		2	7	-	7		7		2	1		
Hyperplasia, reactive			R	NR	NE		R :	IR	NR	NR		
URINARY BLADDER	1 N		R I	NR	N.			IR	NR	NR		
SKIN (Test Site)	- 2	R N	-	-,,,, 		-				J		
Acanthosis			-+	_								
Acute Inflammation										T		
Chronic Inflammation			+				_					1
Crusting												
Deep Pyoderma						_						
Dermal Congestion							_					
Durma! Edema			-+		-			_				
Epidermal Microabscesses, multifoca	11		-+		-							\Box
Hymerkeracosis		}_	+		-							
Liquefactive Degeneration									_		$\neg \neg$	
Necrolysis, epidermal					├							
Parakeratosis					├		-		-			
OTHER LESIONS					T	TO T	NP 2	INP	TN	PIT	TP	
LUNG	I	ון אוי	NP	TNP	113	15 -			 	- - :		
Atelectasis					+		NR	NR	N	R	IR	
STOMACH		NR	NR	NR	` -		.17.		 '			
Congestion, mucosal					+-				+			

KEY: Acc = Accidental Death

DOT = Died on Test FS = Final Sacrifice

MS - Moribund Sacrifice SS - Scheduled Sacrifice

NOT - Tissue Present, No

Diagnosis Tendered

TNP - Tissue Not Present

NR = Tissue Present, Not Remar _ble

AUT - Autolysis

O-NR - Paired Organ, Unilateral Absence, Tissue Present,

Not Remarkable

0- - Unilateral Lesion

Severity

1 - Very Slight

2 - Slight or Smal

3 - Moderate

4 - Severe

Project No. 1443

Analysis of Feed

The guaranteed analyses of feed for Purina Guinea Pig Chow[®], Purina Formulab Chow[®], and Purina Rabbit Chow[®], as provided on the manufacturer's labels, are listed below. No additional analyses of feed were made.

Guaranteed Analysis of Feed

	Type of Purina® Chow							
Nutritional Content	Purina Guinea Pig Chow® 5025 (%)	Purina Formulab Chow® 5008 (%)	Purina Rabbit Chow, Checkers® 5301 (%)					
	18.0	23.0	16.0					
Crude protein, minimum Crude fat, minimum	4.0	6.5	2.0					
Crude fiber, maximum	16.0	4.0	i8.0					
	9.0	8.0	9.0					
Ash, maximum Added minerals, maximum	3.5	2.5	3.6					

Triage of 8(e) Submissions

Date sent to triage:	2/5/96	 	нои	N-CAP	CAP
Submission number: _	12539	î A	TSC	A Inventory: (Y N D
Study type (circle appr	ropriate):	<u></u>		-	,
Group 1 - Dick Cleme	nts (1 copy tota	1)			
ECO	AQUATO				
Group 2 - Ernie Falke	(1 copy total)				
атох 🤇	SBTOX	SEN	w/NEUR		
Group 3 - Elizabeth M	largosches (1 co	opy each)			
STOX	стох	EPI	RTOX	GTOX	
STOX/ONCO	CTOX/ONCO	IMMUNO	CYTO	NEUR	
Other (FATE, EXPO, M	IET, etc.):			,	
Notes:				•	
THIS IS THE ORIGIN	NAL 8(e) SUBM	ISSION; PLEAS	SE REFILE AF	TER TRIAGE	DATABASE ENTRY
entire documen	t: 0 1 2	For Contractor	Use Only	pages <u>/</u>	3, tabs.
Contractor revie	ewer:	.PS	Date:	5/11/9	5

CECATS\TRIAGE TRACKING DBASE ENTRY FORM

Conson	t-oleum	INFORMATION REQUESTED: FLW 0501 NO INFO REQUESTED 0502 INFO REQUESTED (TECH) 0503 INFO REQUESTED (VOL AC 0504 INFO REQUESTED (REPORT DISPOSITION: 0620 REFER TO CHEMICAL SCRE	TIONS) TING RATIONALE) EENING	VOLUNTARY ACTIONS: 0401 NO ACTION RI PORTED 0402 STUDIES PLANNI-DAINDER 0403 NOTIFICATION OF WORKE 0404 LABELMSDS CHANGES 0405 PROCESSALANDLING CHAP 0406 APPJUSE DISCONTINUED 0407 PRODUCTION DISCONTINUE 0408 CONFIDENTIAL	NCJ 2
CHEMICAL NAME:	13 DATE: 09 (<u> </u>	13 20 95 188 168553-00-4	•	
INFORMATION TYPE: 0201 ONCO (HUMAN) 0202 ONCO (ANIMAL) 0203 CELL TRANS (IN VITRO) 0204 MUTA (IN VITRO) 0205 MUTA (IN VIVO) 0206 REPRO/IERATO (HUMAN) 0207 REPRO/TERATO (ANIMAL) 0208 NEURO (HUMAN) 0209 NEURO (ANIMAL) 0210 ACUTE TOX. (HUMAN) 0211 CHR. TOX. (HUMAN) 0212 ACUTE TOX. (ANIMAL) 0213 SUB ACUTE TOX (ANIMAL) 0214 SUB CHRONIC TOX (ANIMAL) 0215 CHRONIC TOX (ANIMAL)	01 02 04 01 02 04	INFORMATION TYPE: 0216 EPI/CLIN 0217 HUMAN EXPOS (PROD CONTAM 0218 HUMAN EXPOS (ACCIDENTAL) 0219 HUMAN EXPOS (MONITORING) 0220 ECO/AQUA TOX 0221 ENV. OCCC/REL/FATE 0222 EMER INCI OF ENV CONTAM 0223 RESPONSE REQEST DELAY 0224 PROD/COMP/CHEM ID 0225 REPORTING RATIONALE 0226 CONFIDENTIAL 0227 ALLERG (HUMAN) 0228 ALLERG (ANIMAL) 0239 METAB/PHARMACO (ANIMAL) 0240 METAB/PHARMACO (HUMAN)	01 62 64 6241	IMMUNO (ANIMAL) IMMUNO (HUMAN) CHEM/PHYS PROP CLASTO (IN VITRO) CLASTO (ANIMAL) CLASTO (HUMAN) DNA DAM/REPAIR PROD/USE/PROC MSDS OTHER	PFC 01 02 04 01 02 04 01 02 04 01 02 04 01 02 04 01 02 04 01 02 04 01 02 04
TRIAGE DATA: NON-CBI INVENTORY YES CAS 5R NO	ONGOING REVIE YES (DROP/REFE NO (CONTINUE)	RBT LOW	CAL CONCERN:	<u>USE:</u> <u>PRODUCTIO</u>	<u>N:</u>
CH2 2K NO	REFFR	нюн		•	

L

Subacute dermal toxicity in rabbits is of low concern. New Zealand White rabbits (4/sex) received dermal doses of 8000 mg/kg/day (converted from mL/kg assuming a density of 1), 5 days/week for two weeks. Death occurred in 2/8 rabbits. All animals exhibited weight loss and erythema and irritation at the test site. Gross necropsy revealed: hepatic swelling and necrosis (1/8), discolored or congested liver (7/8), pale or congested kidneys (5/8), gastrointestinal hemorrhage (1/8), and enlarged spleen (2/8). Microscopic examination revealed slight to severe multifocal hepatic necrosis (7/8), slight to severe hepatic centrilobular vacuolar degeneration (3/8), and slight epithelial hyperplasia of the urinary bladder mucosa (4/8). In addition, the test material produced slight to moderate acanthosis, chronic inflammation, crusting, dermal congestion and edema, and hyperkeratosis at all test sites.